THE ONLY COVID-19 ANTIVIRAL WITH OUTCOMES ACROSS 3 KEY TREATMENT GOALS:

DISEASE PROGRESSION, RECOVERY TIME, AND READMISSION[1,2]

INDICATION

VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients (≥28 days old and weighing ≥3 kg), who are:

- Hospitalized, or
- Not hospitalized, have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

IMPORTANT SAFETY INFORMATION

Contraindication

- VEKLURY is contraindicated in patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any of its components.

Please see additional Important Safety Information within and full Prescribing Information here.

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VEKLURY has retained antiviral activity against Omicron and all other variants tested in vitro[1,3-5]

The antiviral activity of VEKLURY has been tested in vitro against clinical isolates of SARS-CoV-2 variants. These laboratory findings demonstrated that the antiviral activity of VEKLURY is not reduced against these variants:

Omicron	Delta	Alpha	Beta	Gamma
(B.1.1.529/BA.1, BA.2, BA.2.12.1, BA.2.75, BA.4, BA.4.6, BA.5, BF.5, BF.7, BQ.1, BQ.1.1, CH.1.1, XBB, and XBB.1.5)	(B.1.617.2)	(B.1.1.7)	(B.1.351)	(P.1)

Epsilon	Zeta	Iota	Kappa	Lambda
(B.1.429)	(P.2)	(B.1.526)	(B.1.617.1)	(C.37)

Viruses like SARS-CoV-2 continuously evolve as changes in the genetic code occur during replication[6]

To date, known novel virus variants show mutations at different locations in the SARS-CoV-2 spike protein, which is on the outer surface of the virus and can cause decreased affinity of anti–SARS-CoV-2 antibodies.[6-8]

No known SARS-CoV-2 variants have significantly altered the viral RNA polymerase.[3,5]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions

- **Hypersensitivity, including infusion-related and anaphylactic reactions:** Hypersensitivity, including infusion-related and anaphylactic reactions, has been observed during and following administration of VEKLURY; most reactions occurred within 1 hour. Monitor patients during infusion and observe for at least 1 hour after infusion is complete for signs and symptoms of hypersensitivity as clinically appropriate. Symptoms may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diaphoresis, and shivering. Slower infusion rates (maximum infusion time of up to 120 minutes) can potentially prevent these reactions. If a severe infusion-related hypersensitivity reaction occurs, immediately discontinue VEKLURY and initiate appropriate treatment (see Contraindications).

RDV-TP=remdesivir triphosphate.

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VEKLURY disrupts RNA replication[1,9,10]

VEKLURY is an antiviral medication that directly inhibits viral replication of SARS-CoV-2

VEKLURY acts to inhibit the SARS-CoV-2 RNA-dependent RNA polymerase (RdRp), which is essential for viral replication—and thus creation of virions that circulate in the body.

TAKE A CLOSER LOOK AT THE MECHANISM OF ACTION FOR VEKLURY

Please see clinical studies and efficacy data on the following pages.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Increased risk of transaminase elevations:** Transaminase elevations have been observed in healthy volunteers and in patients with COVID-19 who received VEKLURY; these elevations have also been reported as a clinical feature of COVID-19. Perform hepatic laboratory testing in all patients (see Dosage and administration). Consider discontinuing VEKLURY if ALT levels increase to >10x ULN. Discontinue VEKLURY if ALT elevation is accompanied by signs or symptoms of liver inflammation.
- **Risk of reduced antiviral activity when coadministered with chloroquine or hydroxychloroquine:** Coadministration of VEKLURY with chloroquine phosphate or hydroxychloroquine sulfate is not recommended based on data from cell culture experiments, demonstrating potential antagonism, which may lead to a decrease in the antiviral activity of VEKLURY.

Adverse reactions

- The most common adverse reaction (≥5% all grades) was nausea.
- The most common lab abnormalities (≥5% all grades) were increases in ALT and AST.

Please see additional Important Safety Information within and full Prescribing Information here.

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Early use of VEKLURY helped reduce the risk of COVID-19–related hospitalization or death[1,11]

87%

Lower risk of COVID-19–related hospitalization or death from any cause by Day 28

- 0.7% of patients treated with VEKLURY (n=2) compared to 5.3% of patients treated with placebo (n=15) had a COVID-19–related hospitalization or death from any cause by Day 28; HR: 0.13 (95% CI, 0.03 to 0.59), *P* = 0.008
- No deaths were reported in either group by Day 28

The safety profiles of VEKLURY and placebo were comparable

- The most common adverse reaction (≥5%) in patients taking VEKLURY was nausea

> *"Remdesivir is another important option for outpatients with COVID-19."*
>
> — Gottlieb RL, et al. *N Engl J Med.* 2022;386(4):305-315.

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration

— Administration should take place under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible.

- **Treatment duration:**
  - — For patients who **are hospitalized**, VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19.
  - — For patients who are hospitalized and do not require invasive mechanical ventilation and/or ECMO, the recommended treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended up to 5 additional days, for a total treatment duration of up to 10 days.
  - — For patients who are hospitalized and require invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days.
  - — For patients who are **not hospitalized**, diagnosed with mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death, the recommended total treatment duration is 3 days. VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19 and within 7 days of symptom onset for outpatient use.

HR=hazard ratio.

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PINETREE study

VEKLURY significantly reduced risk of progression to severe COVID-19[1,11]

The **PINETREE study (GS-US-540-9012)** was a phase 3, randomized, double-blind, placebo-controlled clinical trial in patients who were not hospitalized, had confirmed positive results for SARS-CoV-2 infection, showed symptoms of mild-to-moderate COVID-19 for ≤7 days, and had at least 1 risk factor for progression to hospitalization.

Patients were randomized to receive VEKLURY (n=279) or placebo (n=283) for 3 days. Patients in the VEKLURY arm received a single loading dose of VEKLURY 200 mg IV on Day 1 followed by once-daily maintenance doses of VEKLURY 100 mg IV on Days 2 and 3. Patients who received, required, or were expected to require supplemental oxygen were excluded from the trial.

Risk factors for disease progression in PINETREE included:

- Hypertension
- Chronic lung disease
- Cardiovascular or cerebrovascular disease
- Diabetes mellitus
- Obesity (BMI ≥30 kg/m^2)
- Immunocompromised state
- Chronic mild or moderate kidney disease
- Chronic liver disease
- Current cancer
- Sickle cell disease

60+ Patients 60 years of age or older were eligible, regardless of whether they had other risk factors

Primary endpoints

The primary efficacy endpoint was a composite of COVID-19–related hospitalization (defined as ≥24 hours of acute care) or death from any cause by Day 28.

The primary safety endpoint was any adverse event.

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Testing prior to and during treatment:** Perform hepatic laboratory and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate.
- **Renal impairment:** No dosage adjustment of VEKLURY is recommended in patients with any degree of renal impairment, including patients on dialysis. VEKLURY may be administered without regard to the timing of dialysis.

Please see additional Important Safety Information within and full Prescribing Information here.

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LEADING THE WAY

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VEKLURY helped shorten time to recovery[1,12]

In the ACTT-1 overall study population, patients experienced

5 DAYS SHORTER RECOVERY TIME WITH VEKLURY

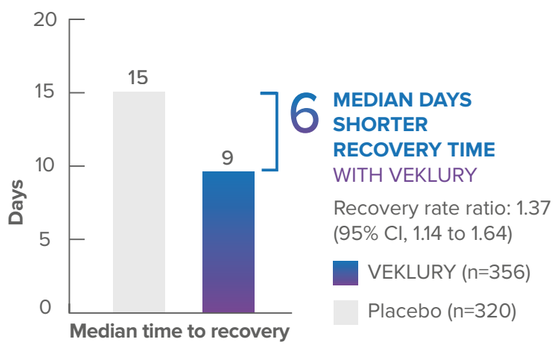
Median 10 days with VEKLURY vs 15 days with placebo; recovery rate ratio: 1.29 (95% CI, 1.12 to 1.49), *P* < 0.001

- Recovery was defined as patients who were no longer hospitalized or hospitalized but no longer required ongoing COVID-19 medical care

Patients treated with VEKLURY recovered faster, regardless of days since symptom onset[12,13]

A prespecified subgroup analysis showed:

Median time to recovery in patients with symptom onset less than or equal to 10 days



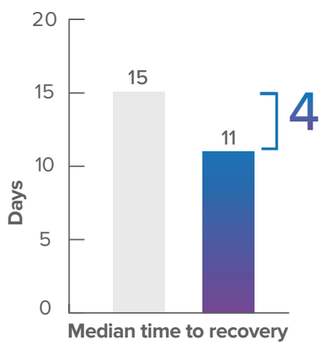
6 MEDIAN DAYS SHORTER RECOVERY TIME WITH VEKLURY

Recovery rate ratio: 1.37 (95% CI, 1.14 to 1.64)

VEKLURY (n=356)

Placebo (n=320)

Median time to recovery in patients with symptom onset greater than 10 days



4 MEDIAN DAYS SHORTER RECOVERY TIME WITH VEKLURY

Recovery rate ratio: 1.20 (95% CI, 0.94 to 1.52)

VEKLURY (n=184)

Placebo (n=199)

VEKLURY is indicated for patients hospitalized with COVID-19, independent of time from symptom onset

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VEKLURY improved clinical outcomes in hospitalized patients across a spectrum of COVID-19 severity[1,12]

The **ACTT-1 study** was a randomized, double-blind, placebo-controlled, phase 3 clinical trial in hospitalized adult patients with confirmed SARS-CoV-2 infection and mild, moderate, or severe COVID-19.

Patients were randomized to receive VEKLURY (n=541) or placebo (n=521) for up to 10 days. Patients in the VEKLURY arm received a single loading dose of VEKLURY 200 mg IV on Day 1 followed by once-daily maintenance doses of VEKLURY 100 mg IV on Days 2 through 10. Treatment with VEKLURY was stopped in patients who were discharged from the hospital prior to the completion of 10 days of treatment.

Patient clinical status was assessed on an 8-point ordinal scale with a higher score indicating greater clinical severity.

Primary endpoint

The primary endpoint was time to recovery within 29 days after randomization. Recovery included hospital discharge for some patients with or without limitations on activities, as defined by ordinal scores 1–3.

- Recovery was defined as patients who were no longer hospitalized or hospitalized but no longer required ongoing COVID-19 medical care

Treatment with VEKLURY earlier in the disease course resulted in the greatest benefit for patients

IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy and lactation

- **Pregnancy:** A pregnancy registry has been established for VEKLURY. Available clinical trial data for VEKLURY in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes following second- and third-trimester exposure. There are insufficient data to evaluate the risk of VEKLURY exposure during the first trimester. Maternal and fetal risks are associated with untreated COVID-19 in pregnancy.
- **Lactation:** VEKLURY can pass into breast milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VEKLURY and any potential adverse effects on the breastfed child from VEKLURY or from an underlying maternal condition. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

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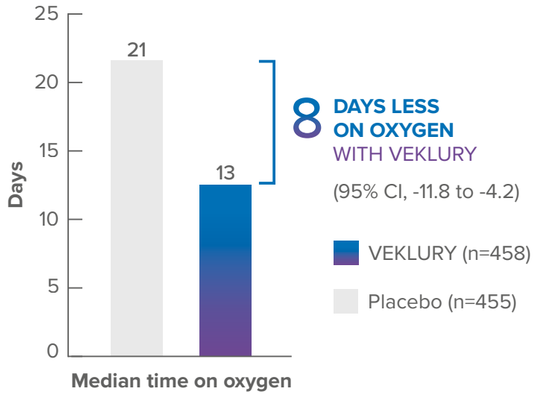
VEKLURY shortened time on oxygen and helped improve clinical status[1,12,13]

VEKLURY reduced median time on oxygen by 8 days in patients who received oxygen at baseline



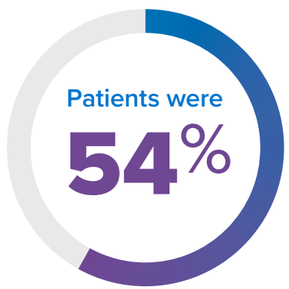
8 DAYS LESS ON OXYGEN WITH VEKLURY

(95% CI, -11.8 to -4.2)

VEKLURY (n=458)

Placebo (n=455)

Patients had a significantly greater likelihood of improvement in clinical status with VEKLURY



more likely to have improved clinical status with VEKLURY vs placebo at Day 15

Improvements were maintained through Day 29; odds ratio for improvement: 1.54 (95% CI, 1.25 to 1.91)

- A key secondary endpoint was clinical status of patients on Day 15 as assessed by an 8-point ordinal scale
- Improvement in clinical status was defined as moving 1 or more points from baseline toward recovery on the ordinal scale

INDICATION

VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients (≥28 days old and weighing ≥3 kg), who are:

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- Not hospitalized, have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

ECMO=extracorporeal membrane oxygenation.

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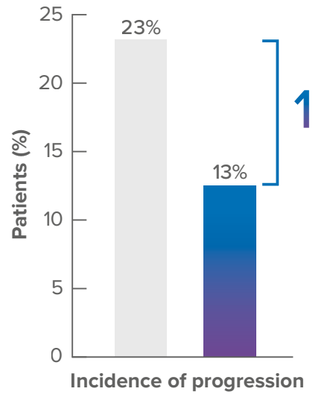
VEKLURY reduced progression to more severe disease, an additional secondary endpoint[1,12,13]

VEKLURY reduced progression to mechanical ventilation or ECMO vs placebo in patients who did not receive either at baseline



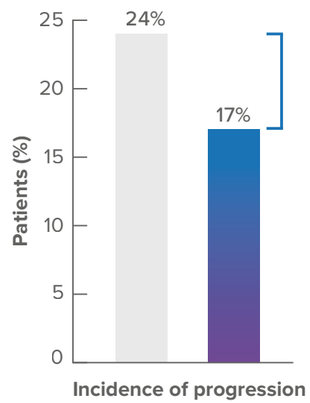
10% ABSOLUTE REDUCTION WITH VEKLURY

(95% CI, -15 to -4)

VEKLURY (n=402)

Placebo (n=364)

VEKLURY reduced incidence of new noninvasive ventilation or high-flow oxygen vs placebo in patients who did not receive either at baseline



7% ABSOLUTE REDUCTION WITH VEKLURY

(95% CI, -14 to -1)

VEKLURY (n=307)

Placebo (n=266)

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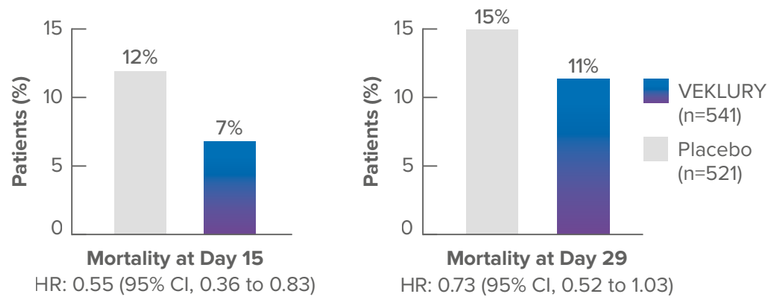
Mortality in the overall population[1,12]

Mortality at Day 29 was a prespecified secondary endpoint

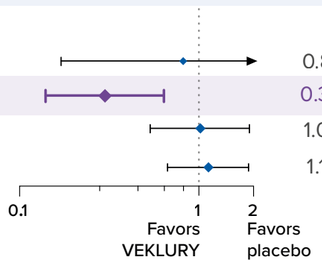
Results in the overall population at Day 29 were not statistically significant.

- The ACTT-1 study was not powered to evaluate a difference in mortality in the overall population



Mortality rates by ordinal scale at Day 29, a post hoc subgroup analysis[1,12,13]

Entire study (Day 29)	Number of deaths/number of patients VEKLURY	Placebo	HR (95% CI)
Ordinal score at baseline			
4	3/75	3/63	0.82 (0.17 to 4.07)
5	9/232	25/203	0.30 (0.14 to 0.64)
6	19/95	20/98	1.02 (0.54 to 1.91)
7	28/131	29/154	1.13 (0.67 to 1.89)



VEKLURY reduced mortality rates at Day 29 in patients on low-flow oxygen at baseline by 70% vs placebo. HR: 0.30 (95% CI, 0.14 to 0.64)

- No difference was demonstrated in the other baseline oxygen status subgroups
- There was no adjustment to control for multiple testing in this post hoc analysis

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindication

- VEKLURY is contraindicated in patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any of its components.

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Adverse reaction frequency and laboratory abnormalities were comparable between VEKLURY and placebo[1]

Comparable frequency of adverse reactions vs placebo

Types of adverse reactions	VEKLURY (n=532) n (%)	Placebo (n=516) n (%)
Any adverse reaction, Grades ≥3	41 (8)	46 (9)
Serious adverse reactions	2 (0.4)*	3 (0.6)
Adverse reactions leading to treatment discontinuation	11 (2)†	15 (3)

Laboratory abnormalities (Grades 3–4) reported in ≥3% of patients

Laboratory parameter abnormality‡	VEKLURY (n=532)	Placebo (n=516)
ALT increased	3%	6%
AST increased	6%	8%
Bilirubin increased	2%	5%
Creatinine clearance decreased§	18%	20%
Creatinine increased	15%	16%
eGFR decreased	18%	24%
Glucose increased	12%	13%
Hemoglobin decreased	15%	22%
Lymphocytes decreased	11%	18%
Prothrombin time increased	9%	4%

*Seizure (n=1), infusion-related reaction (n=1).
†Seizure (n=1), infusion-related reaction (n=1), transaminases increased (n=3), ALT increased and AST increased (n=1), GFR decreased (n=2), acute kidney injury (n=3).
‡Frequencies are based on treatment-emergent laboratory abnormalities graded per Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, Version 2.1, dated July 2017.
§Based on the Cockcroft-Gault formula.

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In a real-world study, patients treated with VEKLURY were significantly less likely to be readmitted across variant periods[2]

A large, real-world, retrospective cohort study examined 30-day, all-cause readmission after COVID-19 hospitalization in adult patients (≥18 years of age) who were treated with VEKLURY vs those not treated with VEKLURY across variant periods from May 2020 through April 2022.

Primary endpoint

The primary endpoint was 30-day, all-cause readmission to the same hospital after being discharged alive from the index COVID-19 hospitalization.*

- Data were examined using multivariate logistic regression. The model adjusted for age, corticosteroid use, variant period, Charlson Comorbidity Index (CCI), maximum oxygenation requirements, and ICU admission during COVID-19 hospitalization
- **This study was sponsored by Gilead Sciences, Inc.**

Study limitations

- Patients readmitted to a different hospital were not accounted for
- Since the model adjusted for multiple variables, patients were not matched
- Patients received at least 1 dose of VEKLURY; model did not account for the number of VEKLURY doses administered†
- Real-world studies should be interpreted based on the type and size of the source datasets and the methodologies used to mitigate potential confounding or bias. Real-world data should be considered in the context of all available data. Results may differ between studies

The patient population included a broad range of:

- Comorbidities
- Supplemental oxygen requirements
- Ages
- Concomitant medications used‡

*Index COVID-19 hospitalization was defined as the first admission to the hospital between May 1, 2020, and April 30, 2022, with a primary discharge diagnosis of COVID-19.
†Refer to the Dosing and Administration section of the full Prescribing Information for dosage recommendations.
‡Other treatments administered at baseline for patients (across both study arms) included corticosteroids, tocilizumab, and baricitinib, as well as combinations of the aforementioned treatments.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions

- **Hypersensitivity, including infusion-related and anaphylactic reactions:** Hypersensitivity, including infusion-related and anaphylactic reactions, has been observed during and following administration of VEKLURY; most reactions occurred within 1 hour. Monitor patients during infusion and observe for at least 1 hour after infusion is complete for signs and symptoms of hypersensitivity as clinically appropriate. Symptoms may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diaphoresis, and shivering. Slower infusion rates (maximum infusion time of up to 120 minutes) can potentially prevent these reactions. If a severe infusion-related hypersensitivity reaction occurs, immediately discontinue VEKLURY and initiate appropriate treatment (see Contraindications).

IMV=invasive mechanical ventilation; NIV=noninvasive ventilation; NSOc=no supplemental oxygen charges.
PINC AI™ is a trademark of Premier, Inc. (formerly Premier Healthcare Database).

Data source

PINC AI™ Healthcare Database: This US hospital–based, service-level, all-payer (commercial, Medicare, Medicaid, others) database **covered approximately 25% of all US hospitalizations from 48 states**.

Study population

- **440,601 patients from 852 hospitals** with a primary diagnosis of COVID-19 and who were discharged alive
- **248,785 VEKLURY patients** were compared to **191,816 non-VEKLURY** patients

Population characteristics

Compared to nonreadmitted patients, readmitted patients:

- **Were older:** median 71 years vs 63 years
- **Had more comorbidities:** CCI ≥4: 36% vs 16%
- **Were more likely to have NSOc:** 42% vs 39%
- **Were less likely to be:**
  - On low-flow oxygen: 40% vs 42%
  - Treated with any VEKLURY: 48% vs 57%
- **Had an equal proportion of:**
  - High-flow oxygen/NIV: 16% vs 16%
  - IMV/ECMO: 3% vs 3%
- **Had comparable length of stay:** median 5 days vs 5 days

Compared to non-VEKLURY patients, VEKLURY patients:

- **Were younger:** median 62 years vs 64 years
- **Were less likely to have NSOc:** 30% vs 52%
- **Were more likely to be on:**
  - Low-flow oxygen: 46% vs 36%
  - High-flow oxygen/NIV: 20% vs 10%
  - IMV/ECMO: 4% vs 2%

See the data on the following pages.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Increased risk of transaminase elevations:** Transaminase elevations have been observed in healthy volunteers and in patients with COVID-19 who received VEKLURY; these elevations have also been reported as a clinical feature of COVID-19. Perform hepatic laboratory testing in all patients (see Dosage and administration). Consider discontinuing VEKLURY if ALT levels increase to >10x ULN. Discontinue VEKLURY if ALT elevation is accompanied by signs or symptoms of liver inflammation.
- **Risk of reduced antiviral activity when coadministered with chloroquine or hydroxychloroquine:** Coadministration of VEKLURY with chloroquine phosphate or hydroxychloroquine sulfate is not recommended based on data from cell culture experiments, demonstrating potential antagonism, which may lead to a decrease in the antiviral activity of VEKLURY.

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Real-world study

Patients treated with VEKLURY had significantly reduced readmission rates across variant periods[2]

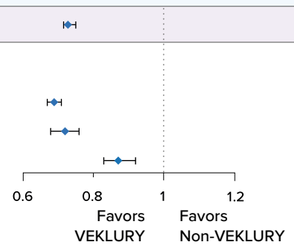
27%

Reduction of 30-day, all-cause readmission was observed with VEKLURY

In the overall cohort, patients treated with VEKLURY were **27% less likely to be readmitted** within 30 days; aOR: 0.73 (95% CI, 0.72 to 0.75), *P* < 0.0001.

30-day, all-cause reduction in readmission was significant across variant periods in index hospitalization (May 2020 through April 2022)

	Readmitted patients/ Total number of patients		Likelihood of 30-day readmission aOR with 95% CI	aOR (95% CI)	*P* value
	VEKLURY	Non-VEKLURY			
Overall cohort	15,780/248,785	17,437/191,816		0.73 (0.72 to 0.75)	< 0.0001
Variant period					
Pre-Delta	7,766/122,560	10,176/109,348		0.69 (0.67 to 0.71)	< 0.0001
Delta	4,256/83,178	3,466/44,215		0.72 (0.68 to 0.76)	< 0.0001
Omicron	3,758/43,047	3,795/38,253		0.87 (0.83 to 0.92)	< 0.0001



IMPORTANT SAFETY INFORMATION (cont'd)

Adverse reactions

- The most common adverse reaction (≥5% all grades) was nausea.
- The most common lab abnormalities (≥5% all grades) were increases in ALT and AST.

Dosage and administration

— Administration should take place under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible.

- **Treatment duration:**
  - — For patients who **are hospitalized**, VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19.
  - — For patients who are hospitalized and do not require invasive mechanical ventilation and/or ECMO, the recommended treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended up to 5 additional days, for a total treatment duration of up to 10 days.

aOR=adjusted odds ratio.

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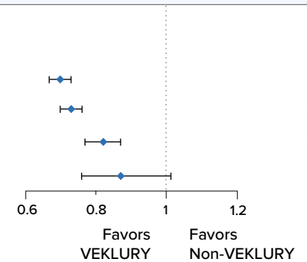
Real-world study

Significantly reduced readmission rates across a broad range of disease severity[2]

30-day, all-cause readmission by maximum oxygenation in index hospitalization

	Readmitted patients/ number of patients		Likelihood of 30-day readmission aOR with 95% CI	aOR (95% CI)	*P* value
	VEKLURY	Non-VEKLURY			
Maximum oxygenation in index hospitalization					
No supplemental oxygen	4,806/73,859	9,055/99,030		0.70 (0.67 to 0.73)	< 0.0001
Low-flow oxygen	7,025/115,923	6,181/68,389		0.73 (0.70 to 0.76)	< 0.0001
High-flow oxygen or NIV	3,379/50,029	1,834/19,815		0.82 (0.77 to 0.87)	< 0.0001
IMV/ECMO	570/8,974	367/4,582		0.87 (0.76 to 1.01)	0.0613



- **This statistically significant reduction was observed for all supplemental oxygen levels, except for patients in the IMV/ECMO group, which did not meet statistical significance due to low sample size in this group**
- The lower readmission rate for VEKLURY patients was observed despite this group having a higher supplemental oxygen requirement during their index COVID-19 hospitalization, as compared to the non-VEKLURY group

Patients treated with VEKLURY who did not receive supplemental oxygen at index hospitalization showed the **greatest reduction in all-cause readmission**

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Treatment duration** (cont'd)**:**
  - — For patients who are hospitalized and require invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days.
  - — For patients who are **not hospitalized**, diagnosed with mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death, the recommended total treatment duration is 3 days. VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19 and within 7 days of symptom onset for outpatient use.

Please see additional Important Safety Information within and full Prescribing Information here.

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VEKLURY has demonstrated safety outcomes in patients with a broad range of renal impairment and COVID-19 severity[1]

Patients may receive VEKLURY regardless of renal impairment severity

NO dosage adjustment of VEKLURY is recommended for patients with any degree of renal impairment (eg, any eGFR)

NO renal laboratory testing is required before or during treatment

UPDATE YOUR HOSPITAL ORDER SETS AND PROTOCOLS SO PATIENTS WITH RENAL IMPAIRMENT CAN CONSISTENTLY ACCESS VEKLURY

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Testing prior to and during treatment:** Perform hepatic laboratory and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate.
- **Renal impairment:** No dosage adjustment of VEKLURY is recommended in patients with any degree of renal impairment, including patients on dialysis. VEKLURY may be administered without regard to the timing of dialysis.

Pregnancy and lactation

- **Pregnancy:** A pregnancy registry has been established for VEKLURY. Available clinical trial data for VEKLURY in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes following second- and third-trimester exposure. There are insufficient data to evaluate the risk of VEKLURY exposure during the first trimester. Maternal and fetal risks are associated with untreated COVID-19 in pregnancy.
- **Lactation:** VEKLURY can pass into breast milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VEKLURY and any potential adverse effects on the breastfed child from VEKLURY or from an underlying maternal condition. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

AKI=acute kidney injury; CKD=chronic kidney disease; ESRD=end-stage renal disease.

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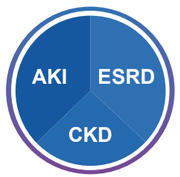
REDPINE study

The only antiviral approved for patients with any stage of renal impairment, including those on dialysis[1,14]

The **REDPINE study (GS-US-540-5912)** was a randomized, double-blind, placebo-controlled, phase 3 clinical trial in hospitalized adult patients with confirmed SARS-CoV-2 infection and a range of renal impairment severity, who received VEKLURY (n=163) or placebo (n=80) plus standard of care. Patients randomized to the VEKLURY arm received a single loading dose of VEKLURY 200 mg IV on Day 1 followed by once-daily maintenance doses of VEKLURY 100 mg IV on Days 2 through 5.

The study population included patients with a broad range of renal disease



- **37% of patients with acute kidney injury** (n=90), defined as a 50% increase in serum creatinine within a 48-hour period that was sustained for ≥6 hours despite having supportive care
- **26% of patients with chronic kidney disease** (n=64); eGFR <30 mL/min
- **37% of patients with end-stage renal disease** (n=89) who required hemodialysis; eGFR <15 mL/min

No new adverse reactions to VEKLURY were identified

Adverse reactions (all grades) were reported in 13 (8%) patients in the VEKLURY group and 3 (4%) patients in the placebo group.

- The most common adverse reactions were nausea (1%), abdominal pain (1%), and diarrhea (1%)
- No patients experienced severe adverse reactions

At baseline, patients had a range of COVID-19 severity

22%
of patients
were on room air

59%
of patients
were on low-flow oxygen

19%
of patients
were on high-flow oxygen

No patients received invasive mechanical ventilation.

Please see additional Important Safety Information within and full Prescribing Information here.

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VEKLURY is administered via intravenous infusion[1]

Recommended dosing

Adult and pediatric patients weighing ≥40 kg should receive:

Loading dose of 200 mg IV

Once-daily maintenance dose of 100 mg IV

Pediatric patients ≥28 days old and weighing ≥3 kg to <40 kg should receive:

Loading dose of 5 mg/kg IV

Once-daily maintenance dose of 2.5 mg/kg IV

Recommended total treatment duration

Flexible infusion time between **30** and **120** minutes

3 days For patients who are NOT hospitalized, have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death

5 days For hospitalized patients NOT requiring invasive mechanical ventilation and/or ECMO

If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days for a total treatment duration of up to 10 days

10 days For hospitalized patients requiring invasive mechanical ventilation and/or ECMO

INDICATION

VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients (≥28 days old and weighing ≥3 kg), who are:

- Hospitalized, or
- Not hospitalized, have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

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Summary

VEKLURY reduced disease progression and recovery time, and demonstrated real-world readmission outcomes across a broad range of COVID-19 severity[1,2,11,12]

87% **Lower risk of COVID-19–related hospitalization** from any cause when treated with VEKLURY vs placebo

- 0.7% of patients treated with VEKLURY (n=279) compared to 5.3% of patients treated with placebo (n=283) had a COVID-19–related hospitalization or death from any cause by Day 28; HR: 0.13 (95% CI, 0.03 to 0.59), $P = 0.008$. No deaths occurred in either arm

5 **Days shorter recovery time** in the overall ACTT-1 study population

- Median 10 days with VEKLURY (n=541) vs 15 days with placebo (n=521); recovery rate ratio: 1.29 (95% CI, 1.12 to 1.49), $P < 0.001$

The adverse reaction frequency of VEKLURY and placebo were comparable in both the ACTT-1 and PINETREE studies. The most common adverse reaction (≥5%) in patients receiving VEKLURY was nausea.

The results above are from PINETREE (N=562), a placebo-controlled trial in nonhospitalized patients with mild-to-moderate COVID-19, and ACTT-1 (N=1062), a placebo-controlled trial in hospitalized patients with mild, moderate, or severe disease.

27% **Reduction in 30-day, all-cause readmission in a real-world study**

- Patients treated with VEKLURY compared to patients who did not receive VEKLURY in the overall cohort; aOR: 0.73 (95% CI, 0.72 to 0.75), $P < 0.0001$; N=440,601*
- Significant 30-day, all-cause readmission reductions were observed across all variant periods (May 2020 through April 2022)

Select limitations: Real-world studies should be interpreted based on the type and size of the source datasets and the methodologies used in order to mitigate potential confounding or bias. Real-world data should be considered carefully in the context of all available data; results may vary between real-world studies.

*Results were from a large, real-world, retrospective cohort study that analyzed data from May 2020 through April 2022 and evaluated 30-day, all-cause readmission to the same hospital after COVID-19 hospitalization.

Please see additional Important Safety Information within and full Prescribing Information here.

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IMPORTANT SAFETY INFORMATION

Contraindication

- VEKLURY is contraindicated in patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any of its components.

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#1 PRESCRIBED ANTIVIRAL

FOR PATIENTS HOSPITALIZED WITH COVID-19[15]

Premier, Inc., and HealthVerity, Inc.; 04/2022 to 04/2023.

The only FDA-approved COVID-19 antiviral:

For use across a **broad spectrum of disease severity**, including those hospitalized for COVID-19[1,16]

For patients with COVID-19 and **any stage of renal disease**, including those on dialysis[1]

For children as young as **28 days old** and weighing at least 3 kg[1]

With no DDI-related contraindications and few expected clinically significant drug interactions[1]

- There is a risk of reduced antiviral activity when coadministered with chloroquine or hydroxychloroquine. Due to potential antagonism observed in vitro, concomitant use of VEKLURY with chloroquine phosphate or hydroxychloroquine sulfate is not recommended

EXPLORE MORE VEKLURY CLINICAL DATA

INDICATION

VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients (≥28 days old and weighing ≥3 kg), who are:

- Hospitalized, or
- Not hospitalized, have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

IMPORTANT SAFETY INFORMATION

Contraindication

- VEKLURY is contraindicated in patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any of its components.

Please see additional Important Safety Information within and full Prescribing Information here.

DDI=drug-drug interaction.

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